

CELADRIN JOINT AND MUSCLE PAIN RELIEVING- menthol cream

Factors Group of Nutritional Products

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Celadrin®

Joint and Muscle Pain Relieving Cream

Drug Facts

Active Ingredients

Menthol (1.25%)

Purpose

Topical Analgesic

Uses

For temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.

Warnings

- **For external use only.**
- Avoid contact with eyes.
- If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of product and consult a physician.
- Do not apply to wounds or damaged skin.
- Do not bandage tightly.
- **Keep out of reach of children.**
- If swallowed, get medical help or contact a poison control center right away.

Directions

Adults and children 2 yrs. of age and older: Apply to affected area not more than 3 to 4 times per day.
Children under 2 yrs. of age: consult a physician.

Other information

Store in a cool, dry place.

Inactive Ingredients

Benzyl Alcohol, Butylparaben, Carbomer, Celadrin® (a proprietary blend of esterified fatty acid carbons), Ethylparaben, Glycerin, Glyceryl Stearate, Isobutylparaben, Lecithin, Methylparaben, *Olea europaea* (Olive) Fruit oil, PEG-100 Stearate, Peppermint Oil, Phenoxyethanol, Potassium Hydroxide, Propylparaben, Tocopheryl Acetate, Water.

Questions?

1-800-430-7898

Distributed by

WN Pharmaceuticals® Inc.,

Everett WA, USA 98203

PRINCIPAL DISPLAY PANEL - 170 g Jar Label

DEEP PENETRATING

InflameAway®

Celadrin®

JOINT & MUSCLE PAIN RELIEVING CREAM

FIMS

GREASELESS

FORMULA

FAST ACTING RELIEF

NET WT. 6 OZ. (170 G)

6
80760 25273 09408
RO

Celadrin Joint & Muscle Pain Relieving Cream can be used safely and with confidence. Celadrin's topical cream is a deep penetrating and fast acting greaseless formula that provides soothing relief.

The International Federation of Sports Medicine (FIMS) www.fims.org goes since 1920 has been to provide the best medical care for Olympic athletes. FIMS has endorsed Celadrin, its first and only official Joint and Muscle Cream, for sports enthusiasts and active adults around the world.

DEEP PENETRATING

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FIMS GREASELESS FORMULA

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Questions? 1-800-430-7898	
<p>www.celadrin.com</p> <p>Made in U.S.A.</p> <p>U.S. Patent #5,569,676</p> <p>Celadrin® is a registered trademark of Inageneix, Inc.</p> <p>Distributed by WMI Pharmaceuticals Inc., Everett, WA, USA 98203 ☎ 1-800-430-7898</p> <p>♻️ Please recycle container.</p> <p>ITEM # 143904</p>	

CELADRIN JOINT AND MUSCLE PAIN RELIEVING

menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54230-356
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	12.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QPII03FV8)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	YELLOW	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54230-356-01	170 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part348	10/01/2012	

Labeler - Factors Group of Nutritional Products (253282701)

Registrant - Lifetech Resources, LLC (662559110)

Establishment

Name	Address	ID/FEI	Business Operations
Lifetech Resources, LLC		622559110	MANUFACTURE(54230-356)